General

Guideline Title

Male external catheters in adults: urinary catheter management.

Bibliographic Source(s)

Geng V, Cobussen-Boekhorst H, Lurvink H, Pearce I, Vahr S. Male external catheters in adults: urinary catheter management. Arnhem (The Netherlands): European Association of Urology Nurses (EAUN); 2016 Mar. 68 p. [62 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Level of evidence (LE) (1a-4) and grade of recommendation (GR) (A-C) are defined at the end of the "Major Recommendations" field.

Complications

- Describe protocols for proper use of male external catheters (MECs). (LE=4, GR=C)
- Observe/inspect the penile skin carefully when changing the MEC. (LE=4, GR=A*)
- Ask/check the patient for latex and other allergies. (LE=4, GR=A*)
- Refer the patient to patch testing if oedema or dermatitis of the penile glans or shaft is observed. (Harmon, Connolly, & Larson, 1995; Milanesi et al., 2013) (LE=4, GR=C)

Products and Materials

In case of urine leakage or retracted penis consider a MEC with special features (see Chapter 6.3 of original guideline document). (LE=4, GR=C)

Principles of Management of Nursing Intervention

- Patients with cognitive impairment should be carefully assessed to determine if they are able to fit and manage a MEC. (Pomfret, 2003) (LE=4, GR=C)
- Measure the length and the circumference of the penis at its widest point to fit the MEC in the correct way. (LE=4, GR=A*)
- Assess the correct length of the inlet tube, taking into account whether the patient is a wheelchair user, a walker or bedridden. (LE=4, GR=A*)

- Assess hand function of the patient and valve taps before choosing a urinary bag for the MEC. (LE=4, GR=C)
- Shorten pubic hair to prevent it being caught in the sheath. (LE=4, GR=C)
- Skin should be observed before fitting a MEC.
- Skin should be observed after MEC is applied. (LE=4, GR=C)
- Avoid creams and powders as they affect the adhesion of the MEC. (Kyle, 2011) (LE=4, GR=C)
- Hydrocolloid could help healing if skin is damaged. (LE=4, GR=C)
- Skin should be observed after removing the MEC. (LE=4, GR=C)
- Change the MEC daily. (Zimakoff et al., 1996; Stelling & Hale, 1996) (LE=4, GR=B)
- Use a non-sterile urinary bag. (LE=4, GR=C)
- Secure the urinary bag to allow free urine flow. (LE=4, GR=C)
- Empty the urinary bag when two-thirds full. (LE=4, GR=C)
- Change the urinary bag at least once weekly or follow local policy. (LE=4, GR=C)
- Follow protocols for collecting urine samples for urine culture from a MEC. (Latour et al., 2013; Nicolle et al., 1988; Ouslander et al., 1987) (LE=2a, GR=B)
- Collect the first voided urine within an hour after MEC change from the sampling. (Latour et al., 2013; Nicolle et al., 1988; Ouslander et al., 1987) (LE=2a, GR=B)

Documentation

- Offer patients an individualised care plan based on the criteria listed in Chapter 11 of the original guideline document, bearing in mind the patient's and caregiver's lifestyle and the impact this will have on the patient's quality of life. (Getliffe et al., 2007) (LE=4, GR=C)
- Complete diary to monitor problems and assess incontinence episodes. (Grabe et al., 2015) (LE=2, GR=B)

An A grade recommendation is a strong recommendation despite level 4 evidence.

Definitions

Level of Evidence (LE)†

Level	Type of Evidence
1a	Evidence obtained from meta-analysis of randomised trials
1b	Evidence obtained from at least one randomised trial
2a	Evidence obtained from one well-designed controlled study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case control studies
4	Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities and case reports

Grade of Recommendation (GR)†

Grade	Type of Evidence - Nature of Recommendations
A	Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial
B	Based on well-conducted clinical studies, but without randomised clinical trials
C	Made despite the absence of directly applicable clinical studies of good quality

†Adapted from Oxford Centre for Evidence-based Medicine (OCBM). OCEBM Levels of Evidence Working Group. The Oxford Levels of Evidence 1. Oxford Cent Evidence-Based Med Oxford: OCEBM; 2011.

Clinical Algorithm(s)

The following clinical algorithms are provided in the original guideline document:

- Management of incontinence with PVR - decision tree
- Flowchart MEC - urinary bag decision tree

Scope

Disease/Condition(s)

- Male urinary incontinence
- Complications of male external catheter use including urinary tract infections (UTIs), irritative and allergic symptoms, compressive symptoms and pressure sores, skin lesions and leakage

Guideline Category

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Geriatrics

Internal Medicine

Nursing

Preventive Medicine

Urology

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Patients

Guideline Objective(s)

- To fill the gap of (evidence-based) information and encourage healthcare professionals to consider option of male external catheters (MECs) more often
- To provide guidance to healthcare professionals, patients and their families for the correct assessment and standard use of MECs in men with urinary incontinence (UI)
- To expand knowledge regarding MEC products and provide practical help in using them
- To prevent unintended harm to patients and to enhance compliance with using MECs

Target Population

Men with urinary incontinence (UI)

Interventions and Practices Considered

1. Protocols for proper use of male external catheters (MECs) and risk assessment/prevention of complications
2. Ensuring knowledge and appropriate choice of products and materials used for MECs
3. Principles of management of nursing intervention
    - Patient assessment, including cognitive infection, ability to walk, and hand function
    - Penis measurement
    - Application of the MEC (skin observation before application, shortening of pubic hair, applying adhesives, skin care)
    - Observation of the applied MEC (skin irritation, leakage, kinking, emptying and changing interval)
    - Removing the MEC
    - Collecting a urine sample from a MEC
4. Individualised care plan
5. Voiding diary to monitor problems and assess incontinence episodes

Major Outcomes Considered

- Complications of male external catheters (MECs) (e.g., urinary tract infection [UTI], allergic reactions)
- Urinary symptoms
- Incidence of urinary incontinence (UI)
- Patient quality of life (QoL)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

The information offered in these guidelines was obtained through a systematic literature search and a review of current procedures undertaken in various member countries of the European Association of Urology Nurses (EAUN).

The initial search was done in December 2014 by a nurse specialist.

Databases

- PubMed
- CINAHL
- Cochrane

Search Terms

- Male external catheters
- Condom catheters
- Urinary sheaths

- External urinary catheter

In July 2015 an additional search was performed by another nurse specialist.

Databases

- EMBASE
- CINAHL
- Cochrane

Search Terms

- Male external catheters
- Condom catheters
- Urinary sheaths
- External urinary catheter
- Complications

As a result of the lack of medical subject headings, (MeSH) the searches were performed with free text for male external catheter and condom catheter as well as urinary sheaths.

The search results were not limited to randomised controlled trials, controlled clinical trials, meta-analyses or systematic reviews. Additional searches were not limited to any level of evidence (LE). For the practical aspects of male external catheter (MEC) application (see Appendices in the original guideline document), brochures from manufacturers were used.

Limitations of the Search

The search and data extraction were based on PICO (patient problem or population [P], intervention [I], comparison [C] and outcome [O]) questions formulated by the Working Group (see Chapter 14 in the original guideline document for a list of the PICO questions).

Limitations of December 2014 Search

- English language
- Adults
- Human studies
- Age ≥19 years
- 2004-2014

Exclusion Criteria during Abstract Selection

- Non-English-language studies
- Conference proceedings
- Paediatric studies
- Use of MECs for diagnostic reasons

It was a policy decision to restrict the search in the way described. After screening the records retrieved from the search of December 2014 (limited to 2004-2014), it was decided to do an additional search without limitation of year. However, it was decided not to use articles from before 2000 for the text on complications because those studies might have been performed with catheters made from material that is no longer used. After review, papers used in the original guidelines (2008) were included where text remained unchanged.

In the process of working with the articles, new references were found and added to the reference list, if they were relevant to the topic and cited in the text.

Number of Source Documents

References included: 62 (see Flowchart 1 in the original guideline document for a breakdown of the number of articles identified and excluded during each stage of the search process)

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence (LE)*

Level	Type of Evidence
1a	Evidence obtained from meta-analysis of randomised trials
1b	Evidence obtained from at least one randomised trial
2a	Evidence obtained from one well-designed controlled study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case control studies
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*Adapted from Oxford Centre for Evidence-based Medicine (OCBM). OCEBM Levels of Evidence Working Group. The Oxford Levels of Evidence 1. Oxford Cent Evidence-Based Med Oxford: OCEBM; 2011.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Rating System

The recommendations provided in this document are based on a rating system modified from that produced by the Oxford Centre for Evidence-based Medicine (OCEBM) in 2011. External data extractors used the European Association of Urology (EAU) data-extraction system for critical assessment of the papers identified.

Whenever possible, the Working Group graded treatment recommendations using a three-grade system (grade of recommendation; GR A-C) and inserted levels of evidence (LE) to help readers assess the validity of the statements made. The aim of this practice is to ensure a clear transparency between the underlying evidence and the recommendations given. This system is further described in the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields. Much of the evidence is weak, therefore, the Working Group decided to upgrade some of the recommendations. Upgraded recommendations are marked 'A*' meaning that the panel has agreed to recommend this even though the LE is 4.

Some of the literature was not easy to grade. However, if the Working Group thought that the information would be useful in practice, it was ranked as LE 4. Low-level evidence indicated that no higher level of evidence was found in the literature when writing the guidelines, but it cannot be regarded as an indication of the importance of the topic or recommendation for daily practice.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Working Group of these updated guidelines consists of nurse specialists, with support from the European Association of Urology Nurses (EAUN) Central Office and a urologist for the Indications chapter.

The scope of these guidelines was established at the start of the writing process. Six PICO (patient problem or population [P], intervention [I], comparison [C] and outcome [O]), questions were posed to guide the literature review process (see Chapter 14 in the original guideline document for a list of the PICO questions).

The Working Group aims to develop guidelines for evidence-based nursing, as defined by Behrens (2004): "Integration of the latest, highest level scientific research into the daily nursing practice, with regard to theoretical knowledge, nursing experience, the ideas of the patient and available resources." The recommendations in these guidelines are based on synthesis of evidence from the articles. The Working Group based the text on the evidence of the articles whenever possible, but if evidence was missing, it was based on best practice and consensus.

Four components that influence nursing decisions can be distinguished: personal clinical experience of the nurse; existing resources; patient wishes and ideas; and results of nursing science. This statement implies that, although literature is important, the experience of nurses and patients is also necessary for decision making. Consequently, it is not only the written guidelines that are relevant for nursing practice.

Rating Scheme for the Strength of the Recommendations

Grade of Recommendation (GR)*

Grade	Type of Evidence - Nature of Recommendations
A	Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial
B	Based on well-conducted clinical studies, but without randomised clinical trials
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*Adapted from Oxford Centre for Evidence-based Medicine (OCBM). OCEBM Levels of Evidence Working Group. The Oxford Levels of Evidence 1. Oxford Cent Evidence-Based Med Oxford: OCEBM; 2011.

Cost Analysis

Cost-effectiveness considerations are best addressed locally and therefore fall outside the remit of these guidelines.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

A blinded review was carried out by specialist nurses, urologists in various countries and patient representatives. The Working Group revised the document based on the comments received and included relevant references received (also from after the search period). A final version was approved by the European Association of Urology Nurses (EAUN) Board and the European Association of Urology (EAU) Executive responsible for EAUN activities.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Getliffe K, Fader M, Allen C, Pinar K, Moore KN. Current evidence on intermittent catheterization: sterile single-use catheters or clean reused catheters and the incidence of UTI. J Wound Ostomy Continence Nurs. 2007 May-Jun;34(3):289-96. [19 references] PubMed

Grabe M, Bartoletti R, Bjerklund Johansen T, et al. EAU guidelines on urological infections. Arnhem (Netherlands): European Association of Urology (EAU); 2015.

Harmon CB, Connolly SM, Larson TR. Condom-related allergic contact dermatitis. The Journal of Urology. 1995 Apr;153(4):1227-8. PubMed

Kyle G. The use of urinary sheaths in male incontinence. Br J Nurs. 2011 Mar-Apr;20(6):338. PubMed

Latour K, PlÃ¼ddemann A, Thompson M, et al. Diagnostic technology: alternative sampling methods for collection of urine specimens in older adults. Fam Med Community Health. 2013;1:43-9.

Milanesi N, Bianchini G, D'Erme AM, Francalanci S. Allergic reaction to condom catheter for bladder incontinence. Contact Dermatitis. 2013 Sep;69(3):182-3. PubMed

Nicolle LE, Harding GK, Kennedy J, McIntyre M, Aoki F, Murray D. Urine specimen collection with external devices for diagnosis of bacteriuria in elderly incontinent men. J Clin Microbiol. 1988 Jun;26(6):1115-9. PubMed

Ouslander JG, Greengold BA, Silverblatt FJ, Garcia JP. An accurate method to obtain urine for culture in men with external catheters. Arch Intern Med. 1987 Feb;147(2):286-8. PubMed

Pomfret I. Back to basics: urinary sheaths. J Community Nurs. 2003;17:22.

Stelling JD, Hale AM. Protocol for changing condom catheters in males with spinal cord injury. SCI Nurs. 1996 Jun;13(2):28-34. PubMed

Zimakoff J, Stickler DJ, Pontoppidan B, Larsen SO. Bladder management and urinary tract infections in Danish hospitals, nursing homes, and home care: a national prevalence study. Infect Control Hosp Epidemiol. 1996 Apr;17(4):215-21. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

These guidelines, in which the Working Groups includes clear illustrations, detailed application procedures and extensive references, will help healthcare professionals to identify potential problem areas in the assessment, application and removal of male external catheters (MECs).

More specifically, these guidelines aim to support healthcare professionals in the prevention of complications of male external catheters, such as urinary tract infections (UTIs), irritative and allergic symptoms, compressive symptoms and pressure sores, skin lesions and leakage, and contribute to improving the quality of life (QoL) of MEC users.

Potential Harms

- The complications related to the application of a male external catheter (MEC) for urinary drainage may be classified as irritative, allergic or compressive in aetiology. In a study of men with spinal cord injury complications related to improper use of MECs were seen in 15% of

patients. Most of the complications resulted from the use of rubber ducts with a penile sheath. Even though MEC products have developed a lot since 1981, complications are still reported (refer to Table 3 in the original guideline document). The risk of complications is inevitably larger in patients with spinal cord injury because of decreased sensation.

- There are conflicting results when it comes to deciding if the risk of urinary tract infection (UTI) is lower in men using MECs compared to indwelling catheters. It is estimated that the incidence of UTI is 40% in men using MECs.

Chapter 5 of the original guideline document contains more detailed information on complications of MEC.

Contraindications

Contraindications

Contraindications

Contraindications to male external catheter (MEC) are few and can be divided into absolute and relative.

Absolute Contraindications

The only absolute contraindication to the use of MEC devices is the known presence of high pressure chronic retention which may be the underlying causative pathology of urinary incontinence (UI). Whilst the use of MEC devices in such a scenario may contain the symptom of UI, it will not influence the high intravesical pressure and resultant impact on renal function and as such a more invasive definitive therapy should be employed.

The use of conventional cystometry will delineate the intravesical pressure but simple renal tract ultrasound scan will demonstrate the hall mark feature of bilateral hydroureteronephrosis even before a decline in renal function is manifest.

Relative Contraindications

Relative contraindications are more reflective of the fact that most clinical scenarios are better managed with alternative means, e.g., low pressure chronic retention or bladder atonia are better managed with either long term catheterisation or intermittent catheterisation but if these are unsuitable or if the patient insists, the use MEC devices are viable since the intravesical pressure is low and thus the upper renal tract is safe. With MEC devices, however, the bladder in these circumstances will fail to drain and increase the risk of urinary tract infection (UTI), stones, etc.; thus whilst possible, this containment method is far from ideal.

Other limiting and relative contraindications for the use of MEC include dermatological issues such as excoriated penile skin, psoriasis and localised allergy to materials used as well as cognitive impairment, as such patient may traumatically avulse the MEC resulting in loss of skin integrity.

Body habitus may form a relative contraindication for some patients as a consequence of a physical inability to apply the device or perhaps visualise the penis thus hindering adequate application. In general patients with a high body mass index (BMI) are at greater risk of this as a combined consequence of blocked vision due to abdominal girth and a prominent supra public fat pad causing loss of visible and accessible penile length upon which to place the MEC.

Qualifying Statements

Qualifying Statements

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The European Association of Urology Nurses (EAUN) Guidelines Working Group has prepared these guidelines to help nurses assess evidence-based management and incorporate the recommendations into their clinical practice. These guidelines are not meant to be prescriptive, nor will adherence to them guarantee a successful outcome in all cases. Ultimately, decisions regarding care must be made on a case-by-case basis by healthcare professionals after consultation with their patients and colleagues, and using their clinical judgement, evidence-based knowledge, and expertise.

Limitations of Document

The EAUN acknowledges and accepts the limitations of this document. It should be emphasised that the current guidelines provide information about treatment of individual patients according to a standardised approach. The information should be considered as providing recommendations

without legal implications. The intended readership is practising nurses and other healthcare professionals. Cost-effectiveness considerations are best addressed locally and therefore fall outside the remit of these guidelines.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Geng V, Cobussen-Boekhorst H, Lurvink H, Pearce I, Vahr S. Male external catheters in adults: urinary catheter management. Arnhem (The Netherlands): European Association of Urology Nurses (EAUN); 2016 Mar. 68 p. [62 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Mar

Guideline Developer(s)

European Association of Urology Nurses - Medical Specialty Society

Source(s) of Funding

This guidelines document was developed with the financial support of Coloplast, Hollister Incorporated and Manfred Sauer GmbH.

Guideline Committee

The European Association of Urology Nurses (EAUN) Guidelines Working Group

Composition of Group That Authored the Guideline

Working Group Members: Veronika Geng, RN MHSc/MNSc (DE) (*Chair*); Susanne Vahr, RN PhD student (DK); Hanny Cobussen-Boekhorst, PhD (NL); Hanneke Lurvink (NL); Ian Pearce (UK)

Financial Disclosures/Conflicts of Interest

Disclosures

Members of the European Association of Urology Nurses (EAUN) Guidelines Working Group have provided disclosure statements of all relationships that might be a potential conflict of interest. This information is stored in the European Association of Urology (EAU) database. The EAUN is a non-profit organisation and funding is limited to administrative assistance and travel and meeting expenses. No honoraria or other reimbursements are provided.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the European Association of Urology Nurses (EAUN) Web site. Also available in Farsi from the EAUN Web site.

Availability of Companion Documents

The following is available:

- EAUN guidelines manual. Arnhem (The Netherlands): European Association of Urology Nurses (EAUN); 2013. 37 pages. Available from the EAUN Web site.

Various resources, including instructions on MEC application by a healthcare professional, troubleshooting, and a voiding diary are provided in the appendices of the original guideline document.

Patient Resources

Appendix B in the original guideline document provides a patient's teaching procedure for applying MEC.

NGC Status

This NGC summary was completed by ECRI Institute on October 3, 2016. The information was reviewed by the guideline developer on November 11, 2016.

Copyright Statement

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